

From: Patrick McGuinness [pmcguinness@fisheriescouncil.org]
Sent: Monday, May 17, 2004 12:26 PM
To: fdadockets@oc.fda.gov
Subject: Docket No. 02N-0278/ Docket No.02N-0276

Dockets Management Branch
US Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852
USA

RE: Dockets No. 02N-0278 /02N-0276- Comments on Prior Notice of Imported Food and Registration of Food Facilities under the Public Health Security and Bioterrorism Preparedness and response act of 2002 - Reopening of theComment Period.

The Fisheries Council of Canada (FCC) is the seafood processor industry trade council in Canada. Our member companies produce the majority of Canadian seafood exported and marketed in the USA. Below are our comments regarding the prior notice and plant registration interim rules.

Docket 02N- 0278: Prior Notice

First of all, we would like to acknowledge the very cooperative spirit adopted by the Food and Drug Administration (FDA)and the Bureau of Customs and Border Protection (CBP) in both the graduated FDA enforcement approach and the efforts of FDA and CBP to harmonized their respective import reporting requirements. As well, the outreach communications efforts by Robert Lake and his colleagues at FDA and officials at the US Embassy in Ottawa is to be commnded. Their efforts were extremely helpful in getting the Canadian industry informed on the requirements and generated considerable efforts by the industry to comply with the requirements.

OVERVIEW

The 2 hours (land/road)/4 hours (air/rail)/8 hours (water) rule was well received by our industry as a reasonable decision regarding the business needs and constraints of industry and the bioterrorism concerns of us all. We encourage FDA and CBP to continue their efforts to have a fully harmonized system with CBP's Advance Electronic Information Rule being the end target i.e. 1 hour (land/road)/ 2hours (rail)/ "wheels up" (air). In the end, there should be only one notification and that notification should meet both FDA and CBP's requirements. This is not only good business but it good security. Multiple paper work for the same shipment will cause confusion, delays, etc. when a food terrorism instance arrises

We believe further education outreach work is required. As such, the education/grace period should be extended before enforcement shifts to monetary penalties mode and then to full enforcement (border refusal). We recommend this not because of responses from our members, who generally report a smooth transmission thus far, but because of the alarming statistics presented in FDA's preliminary compliance report. The high incidence of non-compliance (50% were filed incompletely or inaccurately) is a surprise to industry as border entry under the prior notice regime has proceeded relatively smoothly. I believe the problem has been that FDA has been reviewing the documentation, identifying and recording the non-compliance but not getting back to the exporting company or filer advising them of the error and recommending corrective action. As such, the education/grace period should be extended and this communication disconnect rectified. As a major , if not the major, exporter of seafood to the USA, we want a seamless transition from the grace period to the enforcement period. I am beginning to detect conflicting messages - a positive message from industry in general but a somewhat disturbing message from your preliminary compliance report. We recognize that the extra communications required to accomplish this may be difficult in view of FDA's manpower constraints. The Fisheries Council of Canada offers our resources if they can help in this task.

SPECIFIC RECOMMENDATIONS

- a.. advise filer electronically of any deficiencies, mistakes, etc in their prior notice submission;
- b.. allow the correction of errors in prior notice submissions, provided the corrections are made within the 2/4/8 deadline. Human errors do and will continue to occur in the filing process. Allowing changes without having to cancel the submission will make the process less burdensome and avoid confusion that often results from a cancellation followed by a

re-submission;

c.. advise filer if shipment is refused. The Prior Notice Interim Final Rule provides that the carrier is the point of contact if an article of food is refused. The problem with this requirement is that the carrier is not in a position to resolve the problem when the article of food is refused. The carrier has temporary possession of the product and has little, if any, resources or incentive to resolve the refusal. The exporter, the importer, or ultimate consignee has an ownership interest in the refused food and a strong economic incentive to resolve the refusal swiftly. The exporter, importer, the ultimate consignee, are also in the best position to export or destroy the refused food if the prior notice defects cannot be corrected. Delaying the notification to the exporter, the importer, ultimate consignee, and filer, unduly hinders the resolution.

Docket No. 02N-0276: Registration of Food Facilities

This rule has been relatively easy for the Canadian industry to meet as all plants exporting to the USA are registered with Canada's food inspection agency and have a mandatory HACCP plus quality control system (QMP) that, in fact, has tougher requirements regarding traceability, recall, and record keeping requirements than the requirements under the Bioterrorism Act. However, we do have one recommendation.

a.. For Canada, eliminate the "US Agent" requirement. Our companies are generally identifying an emergency contact and the required "US Agent" contact. As stated above, if FDA has a terrorism concern with a shipment the Agency should be in direct contact with the company that bought the ingredients, processed the product, and shipped it to the US border. Dealing with and through a third party "US Agent" slows and complicates the investigation. While we understand there may be WTO concerns with exempting Canada, there may be allowable provisions in NAFTA. We would also understand that if the US Agent requirement is eliminated that there would be a requirement that the emergency contact be able to communicate in the English language.

In conclusion, these are difficult times and we recognize that the way we do business must be updated to take into account changes in our society. The Fisheries Council of Canada is prepared to work with FDA and CBP to achieve increased food and trade security. We request that the above comments and recommendations are considered as the Agency moves forward in finalizing the rules under the Bioterrorism Act.

Yours truly,

Patrick McGuinness
President
Fisheries Council of Canada
38 Antares Drive, Suite 110
Ottawa, ON K2E 7V2
tel: 613-727-7450
fax 613-727-7453